



## MEDICATION POLICY

**Generic Name:** Tenofovir Alafenamide

**Therapeutic Class or Brand Name:** Vemlidy®

**Applicable Drugs (if Therapeutic Class):** N/A

Preferred: Entecavir (generic), Tenofovir Disoproxil Fumarate (generic)

Non-Preferred: Vemlidy®

**Date of Origin:** 7/31/2018

**Date Last Reviewed/Revised:** N/A

**GPI Code:** 1235208320

### **Prior Authorization Criteria (may be considered medically necessary when criteria I through III are met):**

- I. Patient is 18 years of age or older and ONE of the following criteria (A - D) is met:
  - A. Patient has documented diagnosis of chronic hepatitis B virus infection and has compensated liver disease
  - B. Patient is post-liver transplantation with a HBcAg-positive graft while patient was HBsAg-negative prior to transplant (Note: HBcAg = hepatitis B core antigen; HBsAg = hepatitis B surface antigen)
  - C. Patient is post-liver transplantation and had documented chronic hepatitis B infection prior to transplant
  - D. Patient with prior history of hepatitis B infection who is undergoing immunosuppression related to solid organ transplantation
- II. Prescriber is a Gastroenterologist, Infectious Disease Specialist, or Hepatologist.
- III. Patient cannot take entecavir or tenofovir disoproxil fumarate due to prior treatment failure, adverse effects, or contraindications

### **Exclusion Criteria:**

- N/A

### **Other Criteria:**

- Patient must have a recent documented negative test for HIV-1 infection, unless Vemlidy is being prescribed in combination with other antivirals as part of an HIV-1 co-infection treatment regimen

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### Quantity/Days Supply Restrictions:

- 30 tablets or 630mls per 30 days.

### Approval Length:

- **Authorization:** 1 year.
- **Re-Authorization:** An updated letter of medical necessity or progress notes showing current medical necessity criteria are met and that the medication is effective.

### Appendix:

N/A

### References:

1. [https://www.gilead.com/~media/files/pdfs/medicines/liver-disease/vemlidy/vemlidy\\_pi.pdf?la=en](https://www.gilead.com/~media/files/pdfs/medicines/liver-disease/vemlidy/vemlidy_pi.pdf?la=en).
2. <https://aasldpubs.onlinelibrary.wiley.com/doi/10.1002/hep.29800>
3. Medispan

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<b>Historical Tracking Of Changes Made To Policy</b>	
12/1/2017	1. Policy reviewed: no changes made.
9/13/2016	1. <b>Added</b> “ <a href="http://onlinelibrary.wiley.com/doi/10.1002/hep.28156/epdf">http://onlinelibrary.wiley.com/doi/10.1002/hep.28156/epdf</a> ” <b>under References.</b>
2/24/2015	<ol style="list-style-type: none"> <li>1. <b>Changed</b> “N/A” to “Preferred: Entecavir tablets (generic); Non-Preferred: Baraclude® tablets, Baraclude® oral solution” <b>under Applicable Drugs (if Therapeutic Class).</b></li> <li>2. <b>Changed</b> “Minimum age requirement: 16 years old” to “Minimum age requirement: 2 years old” <b>under Prior Authorization Criteria.</b></li> <li>3. <b>Added</b> “Non-preferred products (i.e. Baraclude® tablets, Baraclude® oral solution) require a documented clinical reason containing details as to why generic entecavir is not appropriate or is contraindicated” <b>under Prior Authorization Criteria.</b></li> <li>4. <b>Changed</b> “30 tablets or 600ml per 30 days” to “30 tablets or 630mls per 30 days” <b>under Quantity/Days Supply Restrictions.</b></li> <li>5. <b>Added</b> “<a href="http://www.aasld.org/sites/default/files/guideline_documents/ChronicHepatitisB2009.pdf">http://www.aasld.org/sites/default/files/guideline_documents/ChronicHepatitisB2009.pdf</a>” <b>under References.</b></li> </ol>
2/13/2014	<ol style="list-style-type: none"> <li>1. <b>Adapted policy to new format.</b></li> <li>2. <b>Added GPI Code.</b></li> <li>3. <b>Changed criterion I under Prior Authorization Criteria from:</b>  “Documented diagnosis of Chronic Hepatitis B virus infection”  <b>to:</b>  “Documented diagnosis of Chronic Hepatitis B virus infection with evidence of active viral replication and ONE of criteria A OR B is met: A. Evidence of persistent elevations in serum aminotransferases (ALT or AST); B. Histologically active disease”.</li> <li>4. <b>Updated references</b> to include Medi-Span.</li> </ol>

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